Registration Decision RD2015-30

Mono- and Di-potassium Salts of Phosphorus Acid (Rampart)

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Registration Decision for Mono- and Di-Potassium Salts of Phosphorous Acid

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is granting full registration for the sale and use of Rampart Technical and Rampart Fungicide, containing the technical grade active ingredient mono- and di-potassium salts of phosphorous acid, to suppress downy mildew in greenhouse cucumbers.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

Rampart Technical (Registration Number 30653) and Rampart Fungicide (Registration Number 30654) are fully registered for use in Canada on certain field grown vegetables and fruit, as well as for post-harvest treatment on stored potatoes. The original review for Rampart Technical and Rampart Fungicide can be found in Proposed Registration Decision PRD2012-26, *Mono- and Di-Potassium Salts of Phosphorous Acid (Rampart)* and Registration Decision RD2013-05, *Mono- and Di-Potassium Salts of Phosphorous Acid (Rampart)*. The active ingredient, mono- and di-potassium salts of phosphorous acid, is fully registered for use in greenhouses in Canada; however, the current applications represent a major new use in greenhouses for this source of the active ingredient.

These products were first proposed for registration of the major new use in the consultation document[1] Proposed Registration Decision PRD2015-23, *Mono- and Di-Potassium Salts of Phosphorous Acid (Rampart)*. This Registration Decision[2] describes this stage of the PMRA's regulatory process for the major new use of mono- and di-potassium salts of phosphorous acid and summarizes the Agency's decision and the reasons for it. The PMRA received no comments on PRD2015-23. This decision is consistent with the proposed registration decision stated in PRD2015-23.

For more details on the information presented in this Registration Decision, please refer to the Proposed Registration Decision PRD2015-23, *Mono- and Di-Potassium Salts of Phosphorous Acid (Rampart)* that contains a detailed evaluation of the information submitted in support of this registration.

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1 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

2 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable[3] if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its conditions of registration. The Act also requires that products have value[4] when used according to label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (for example, children) as well as organisms in the environment. These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticides and Pest Management portion of Health Canada's website at healthcanada.gc.ca/pmra.

What Is Mono- and Di-Potassium Salts of Phosphorous Acid?

Mono- and di-potassium salts of phosphorous acid (commonly known as phosphorous acid) are phosphonate fungicides belonging to the Group 33 class of fungicides as designated by the Fungicide Resistance Action Committee. It may inhibit the metabolism of susceptible fungal pathogens, and stimulate the plant's natural defence response to pathogen attack. Mono- and di-potassium salts of phosphorous acid are currently registered in Canada as a foliar fungicide on certain vegetables and fruits, and a post-harvest treatment on stored potatoes.

Health Considerations

Can Approved Uses of Mono- and Di-Potassium Salts of Phosphorous Acid Affect Human Health?

Mono- and di-potassium salts of phosphorous acid is unlikely to affect human health when used according to label directions.

Exposure to mono- and di-potassium salts of phosphorous acid may occur when handling and applying the product. When assessing health risks, two key factors are considered: the levels where no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). Only uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

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3 "Acceptable risks" as defined by subsection 2(2) of *Pest Control Products Act.*

4 "Value" as defined by subsection 2(1) of *Pest Control Products Act* "... the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (*a*) efficacy; (*b*) effect on host organisms in connection with which it is intended to be used; and (*c*) health, safety and environmental benefits and social and economic impact".

Mono- and di-potassium salts of phosphorous acid are of low acute toxicity, irrespective of the route of exposure, and mildly irritating to the eyes. The precautionary label statement indicating that contact with skin, eyes, and clothing must be avoided, and the personal protective equipment statement that applicators and other handlers must wear a long-sleeved shirt, long pants, gloves, shoes plus socks, and protective eyewear are effective mitigative measures to reduce the risk associated with the use of mono- and di-potassium salts of phosphorous acid.

Residues in Water and Food

Dietary risks from food and water are not of concern.

Dietary risk to humans is considered negligible based on a long history of use and the low toxicity of the end-use product. The available literature suggests that there is no toxicological concern from ingestion of the end-use product residues.

It is anticipated that the use of mono- and di-potassium salts of phosphorous acid in Canada on greenhouse cucumber will not pose a risk to any segment of the population, including infants, children, adults and seniors, from consumption of produce from treated crops. The end-use product is registered for field uses in Canada to suppress downy mildew in brassica leafy vegetables, grapes and blackberry, as well as for field use and post-harvest storage treatment to suppress late blight and pink rot in potatoes. PMRA did not specify MRLs (maximum residue levels) for mono- and di-potassium salts of phosphorous acid for the registered field uses.

No risk due to exposure from drinking water is anticipated as the end-use product is for greenhouse application.

Risks in Residential and Other Non-Occupational Environments

Estimated risk for residential and other non-occupational environments is not of concern.

Risk to people from residential and other non-occupational environments is not expected as the new use is for greenhouse application, and due to the low toxicity of mono- and di-potassium salts of phosphorous acid.

Occupational Risks From Handling Rampart Fungicide

Occupational risks are not of concern when Rampart Fungicide is used according to the label directions, which include protective measures.

Precautionary (for example, wearing of personal protective equipment) and hygiene statements on the label are considered adequate to protect individuals from occupational exposure. Since the application is done in a greenhouse by commercial applicators, exposure to bystanders is expected to be negligible.

Environmental Considerations

What Happens When Mono- and Di-Potassium Salts of Phosphorous Acid Is Introduced Into the Environment?

Mono- and di-potassium salts of phosphorous acid are not expected to pose an unacceptable risk to the environment when used according to label directions as a fungicide in a greenhouse.

Mono- and di-potassium salts of phosphorous acid can enter the environment when Rampart Fungicide is used as a foliar-spray for food crops in greenhouses. Overall inputs to soil and water are considered to be less than the currently registered agricultural applications of this pesticide (in other words, field crops).

Mono- and di-potassium salts of phosphorous acid are not expected to pose an unacceptable risk to non-target terrestrial and aquatic species from use in greenhouses. This is based on the low toxicity to tested organisms and because environmental exposure is expected to be limited from use in greenhouses.

Value Considerations

What Is the Value of Rampart Fungicide

Mono- and di-potassium salts of phosphorous acid, the active ingredients in Rampart Fungicide, suppress downy mildew in greenhouse cucumbers.

Rampart Fungicide, containing mono- and di-potassium salts of phosphorous acid, has previously demonstrated to be effective against certain pathogens that cause downy mildew on brassica leafy vegetables, grapes and blackberry. It has now been demonstrated to suppress downy mildew on greenhouse cucumbers, which is an important disease to manage in greenhouse production. Certain conventional and non-conventional fungicides are registered on greenhouse cucumbers to control or suppress downy mildew. The registration of Rampart Fungicide adds an additional non-conventional product which will contribute to the disease management options for downy mildew for greenhouse cucumber growers, and a rotational alternative, which contributes to resistance management. Rampart Fungicide can also be easily integrated into existing integrated pest management programs on greenhouse cucumbers.

Measures to Minimize Risk

Registered pesticide product labels include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

The key risk-reduction measures on the label of Rampart Fungicide to address the potential risks identified in this assessment are as follows:

Key Risk-Reduction Measures

Human Health

Although the toxicological profile of the end-use product raises no major hazards of concern, to ensure bystander protection and mitigate postapplication exposure of workers, the end-use product label is required to include the precautionary statements, "Keep unprotected persons out of the treated areas in a greenhouse for the duration of the treatment period" and "Allow entry or re-entry to greenhouse only after thorough ventilation and spray mist has cleared and the treated surface has dried."

Environment

Precautionary label statements that are required for all commercial products will be required.

Other Information

The relevant test data on which the decision is based (as referenced in PRD2015-23, *Mono- and Di-Potassium Salts of Phosphorous Acid (Rampart)*) are available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa). For more information, please contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra.infoserv@hc-sc.gc.ca).

Any person may file a notice of objection[5] regarding this registration decision within 60 days from the date of publication of this Registration Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticides and Pest Management portion of the Health Canada's website (Request a Reconsideration of Decision) or contact the PMRA's Pest Management Information Service.

[5] As per subsection 35(1) of the *Pest Control Products Act*.